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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CR-18-00258-EJD JOINT STATUS MEMORANDUM

The parties in the above-captioned matter hereby file this joint status memorandum in advance of the hearing set for January 13, 2020.

I. Government's Statement

On November 4, 2019, the Court held a hearing on the defendants' motion to compel six categories of documents in the possession of CMS and FDA. On November 5, 2019, the Court issued an order finding that "the Prosecution has knowledge of and access to the at-issue documents [and] order[ing] the Prosecution to produce the documents discussed below as part of their Rule 16 obligation, and to assist [FDA and CMS] however possible to ensure the timely production of documents." The Court ordered that FDA shall run searches of all of its custodians' documents using the following terms: "LDT", "Laboratory Developed Test", "Theranos", "fingerstick" or "finger stick", and "nanotainer". The Court further "order[ed] [FDA and CMS] and the Prosecution to complete the production of documents by December 31, 2019."

In addition, the Court ordered FDA and CMS to "continue their investigations of [certain] issues [relating to their productions] and shall disclose the procedures and results of their investigations to the parties no later than November 26, 2019." And it ordered the parties to meet and confer about "(a) whether the Agencies have or will produce employee text messages, (b) any deficiencies in FDA's production that are attributable to FDA's instruction to employees to manually search for responsive documents instead of forensically searching for, collecting, and reviewing documents, (c) the terms the Agencies use to search for and collect potentially responsive documents, and (d) FDA's redactions to documents and withholding of duplicate documents."

With respect to CMS, on December 31, 2019, the government completed its production of documents in the possession, custody, and control of CMS responsive to the six categories and the Court's order. The government's search included a search of hardcopy documents and text messages in the agency's possession, custody, and control. To the best of its knowledge, the government has produced all documents in the possession, custody, and control of CMS responsive to the six categories and the Court's order.

Pursuant to the Court's order, CMS and FDA made disclosures to the parties, which are attached as Exhibits A and B.

As set forth in the government's motion to extend time [ECF No. 215], the government needs additional time to complete its production of documents in the possession, custody, and control of FDA.

The defendants have opposed the motion. ECF Nos. 216 & 217. The government intends to file a reply brief on January 9, 2020.

II. Defendants' Statement

A. The Status of FDA/CMS Productions.

The government conceded its noncompliance with the Court's November 5, 2019 Order in its eleventh-hour motion seeking relief from that Order's deadlines governing the production of FDA documents. *See* Dkt. No. 215. Defendants' positions on the adequacy of the government's efforts at compliance are more fully set forth in their oppositions to the government's motion, *see* Dkt. Nos. 216, 217, and need not be reiterated here except to note that the government made its only production under the November 5 Order on December 31, 2019, what was supposed to be the final deadline for production of all agency documents. That production contained a large amount of data that Defendants have only recently loaded onto their databases but an initial review has identified highly relevant documents that had not previously been produced.

The bulk of the agency documents remain to be produced. According to the government, the December 31 production was comprised of data from 15 FDA custodians amounting to approximately 93.959 GB of Outlook 365 email data. *See* Dk. No. 215-1 at ¶¶ 7, 8 (Decl. of R. Leach). The government estimates that email data from the next tranche of "up to 12" FDA custodians alone may be three times as large ("up to 350 GB"). *Id.* ¶ 9. That still leaves most of the FDA custodians (51 out of 78) unaccounted for. Extrapolating from these trends, it is clear that the defense does not have even close to half of the documents responsive to the six categories in the Court's Order. The government's estimates illustrate how its request for an extension would require Defendants to review multiple voluminous productions long after the original deadline and, if the government's motion is granted, potentially mere weeks before trial begins or thereafter. Like the December 31 production, these later productions are likely to contain documents critical to the defense. Defendants respectfully submit that this is not a practicable approach. *See generally* Dkts. Nos. 216, 271. Defendants need access to these documents now to prepare for trial.

B. Document Preservation Issues.

The November 5 Order also required the government to investigate issues surrounding the

FDA's failure to preserve email files from key FDA custodian Alberto Gutierrez, and to update the defense by November 26, 2019. Dkt. No. 174 at 4 (Nov. 5 Order). On November 26, counsel for the FDA stated the following (*see* Ex. B (11.26.19 Letter from M. Norton)):

> FDA's e-discovery team confirmed that the PST file containing Mr. Gutierrez's email was damaged and could not be repaired by any tools available to FDA. Indeed, the partially-visible emails (and some fully-visible emails) in Mr. Gutierrez's custodian file were the extent of what FDA's e-discovery team was able to recover from the damaged PST file by using recovery software available to it. FDA's e-discovery team additionally relayed that the creation of the PST file from Mr. Gutierrez's emails at the time of his departure was an automated process run by a technical script, and that no errors were reported by the script for Mr. Gutierrez's file. The e-discovery team was thus unable to determine whether the PST file became damaged at the time of its creation (despite the lack of script error notification) or at some subsequent time. Moreover, the e-discovery team was able to confirm that there is no evidence or indication that the damaged PST file is the result of any action or inaction by Mr. Gutierrez or anyone else at FDA.

The FDA thus has concluded the files have been "damaged" such that they cannot be "repaired by any tools available to FDA." In other words, they have not been preserved. Beyond that, the FDA's letter merely reports what it does not know—it does not know when the PST file "became damaged"; it does not know how the file "became damaged"; and it does not know whether the damage "is the result of any action or inaction" by its employees. And, although it claims there is "no evidence or indication" of malfeasance, the FDA does not explain what steps were taken or what "evidence" was reviewed to reach this conclusion. There is no more detail in the FDA's November 26 letter than what it provided at the November 4 conference prior to the Court ordering further investigation and reporting to the defense.

When counsel for Ms. Holmes sought additional information about the processes involved in the FDA's investigation from DoJ, the government responded that it "does not have direct knowledge of FDA's document management practices." *See* Ex. C (1.6.20 email from R. Leach). That disclaimer of knowledge and responsibility is in tension with the fact that the DoJ ordered the FDA to preserve these documents according to a detailed protocol. *See id.* (1.8.20 email from L. Wade). But in any event, the government's hands-off approach does not align with this Court's order for "the Agencies, the Prosecution, and Defendants to meet and confer" on this issue, and for the DoJ to "assist the agencies however possible" in the timely production of documents that fall under the DoJ's Rule 16 obligations. Dkt. No. 174 at 3-4.

Defendants' questions on these points are simple and should be easy to answer. Why wasn't Mr. Gutierrez' Theranos-related evidence properly preserved at the time the DoJ ordered FDA to preserve it? What steps have been taken to try to recover the files? What "tools available to the FDA" were used? Is it still possible that the data can be restored by use of other, better tools, or by recovering the data from back-up tapes or other storage media? Defendants require more transparency so that they may confer with their own technical experts on whether they would agree with FDA's conclusion that there is nothing that can be done—at least "with tools available to FDA"—to recover the damaged files. Because of Mr. Gutierrez' key role in the case, these questions are of utmost importance. And because of the approaching trial date, they are also of the utmost urgency. Under this Court's November 5 Order, Defendants are entitled to more transparency than they thus far have received.

DATED: January 9, 2020

Respectfully submitted,

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Acting Under Authority Conferred
By 28 U.S.C. § 515

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DATED: January 9, 2020

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